UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022
or

□ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number **001-15771**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-0221517**
(State or Other Jurisdiction of incorporation or Organization	(I.R.S. Employer Identification No.)

1330 Avenue of the Americas, 33rd Floor, New York, NY 10019
(Address of principal executive offices, zip code)

(646) 813-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ABEO	Nasdaq Capital Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □
Non-accelerated filer ☒
Emerging growth company □

Accelerated filer □
Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial standards provided pursuant to Section 13(a) of the Exchange Act. □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☒

The number of shares outstanding of the registrant's common stock as of November 7, 2022 was 17,175,799 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended September 30, 2022

INDEX

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains statements that express management's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "expects," "anticipates," "intends," "plans," "believes," "could," "would," "seeks," "estimates," and variations of such words and similar expressions, and the negatives thereof, are intended to identify such forward-looking statements. Such "forward-looking statements" speak only as of the date made and are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by management that are difficult to predict. Various factors, some of which are beyond the Company's control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In addition, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as may otherwise be required by the federal securities laws.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in forward-looking statements due to a number of factors. These statements include statements about: our plans to submit a Biologics License Application for EB-101 and the timing thereof; the expected benefits of EB-101 being granted Orphan Drug and Rare Pediatric Disease designations by the FDA; our plans to continue development of AAV-based gene therapies designed to treat ophthalmic and other diseases and next-generation AAV-based gene therapies; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals; our pipeline of product candidates; our belief that EB-101 could potentially benefit patients with RDEB; development of our novel AAV-based gene therapy platform technology; our belief in the adequacy of the clinical trial data from our VIITAL™ clinical trial, together with the data generated in the program to date, to support regulatory approvals; our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies; our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing; our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; our estimates regarding the size of the potential markets for our product candidates, the strength of our commercialization strategies and our ability to serve and supply those markets; and future economic conditions or performance.

Important factors that could affect performance and cause results to differ materially from management's expectations are described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: our ability to successfully submit a Biologics License Application for EB-101 and the outcome thereof; our ability to find a potential commercialization partner for EB-101; our ability to access our existing at-the-market sale agreement; our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required; our ability to obtain additional equity funding from current or new stockholders; the potential impacts of global healthcare emergencies, such as pandemics, on our business, operations, and financial condition; our ability to out-license technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors, including under our existing at-the-market sale agreement; the outcome of any interactions with the U.S. Food and Drug Administration ("FDA") or other regulatory agencies relating to any of our products or product candidates; our ability to continue to secure and maintain regulatory designations for our product candidates; our ability to develop manufacturing capabilities compliant with current good manufacturing practices for our product candidates; our ability to manufacture cell and gene therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; and our ability to meet our obligations contained in license agreements to which we are party.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,733	$ 32,938
Short-term investments	12,434	12,086
Restricted cash	5,338	5,891
Accounts receivable	—	3,000
Other receivables	1,047	—
Prepaid expenses and other current assets	945	2,377
Total current assets	25,497	56,292
Property and equipment, net	6,606	12,339
Right-of-use lease assets	6,638	9,403
Licensed technology, net	—	1,384
Other assets	20	168
Total assets	$ 38,761	$ 79,586
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,748	$ 4,325
Accrued expenses	4,121	5,585
Current portion of lease liability	1,810	1,818
Current portion of payable to licensor	4,921	4,599
Deferred revenue	—	296
Total current liabilities	12,600	16,623
Payable to licensor	4,064	3,828
Other long-term liabilities	200	200
Long-term lease liabilities	6,484	7,560
Total liabilities	23,348	28,211
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 7,671,351 and 5,888,217 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	77	1,472
Additional paid-in capital	709,590	705,570
Accumulated deficit	(694,210)	(655,640)
Accumulated other comprehensive loss	(44)	(27)
Total stockholders' equity	15,413	51,375
Total liabilities and stockholders' equity	$ 38,761	$ 79,586

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Revenues:				
License and other revenues	$ —	$ —	$ 1,346	$ —
Expenses:				
Royalties	—	—	350	—
Research and development	5,490	9,056	22,693	25,923
General and administrative	3,890	5,816	11,574	17,261
Impairment of licensed technology	—	—	1,355	—
Impairment of right-of-use lease asset	—	—	1,561	—
Impairment of construction-in-progress	—	—	1,792	—
Total expenses	9,380	14,872	39,325	43,184
Loss from operations	(9,380)	(14,872)	(37,979)	(43,184)
Gain on settlement with licensor	—	6,743	—	6,743
PPP loan payable forgiveness income	—	1,758	—	1,758
Interest income	72	7	103	35
Interest expense	(157)	(683)	(558)	(3,603)
Other income (expense)	(19)	3	(136)	(2)
Net loss	$ (9,484)	$ (7,044)	$ (38,570)	$ (38,253)
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	—	(3,782)	—
Net loss attributable to Common Shareholders	$ (9,484)	$ (7,044)	$ (42,352)	$ (38,253)
Basic and diluted loss per common share	$ (1.48)	$ (1.80)	$ (7.05)	$ (9.93)
Weighted average number of common shares outstanding – basic and diluted	6,421,245	3,924,024	6,009,902	3,853,318
Other comprehensive income (loss):				
Change in unrealized gains (losses) related to available-for-sale debt securities	(4)	1	(11)	10
Foreign currency translation adjustments	(6)	(9)	(6)	(9)
Comprehensive loss	$ (9,494)	$ (7,052)	$ (42,369)	$ (38,252)

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

Three months ended September 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2022	—	$ —	—	$ —	5,870,375	$ 1,467	$ 703,379	$ (684,726)	$ (34)	$ 20,086
Stock-based compensation expense	—	—	—	—	—	—	632	—	—	632
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	—	—	—	—	1,038,134	10	4,179	—	—	4,189
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax witholding settlement	—	—	—	—	762,842	8	(8)	—	—	—
Reverse stock-split adjustment	—	—	—	—	—	(1,408)	1,408	—	—	—
Net loss	—	—	—	—	—	—	—	(9,484)	—	(9,484)
Other comprehensive loss	—	—	—	—	—	—	—	—	(10)	(10)
Balance at September 30, 2022	—	$ —	—	$ —	7,671,351	$ 77	$ 709,590	$ (694,210)	$ (44)	$ 15,413

Nine months ended September 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2021	—	$ —	—	$ —	5,888,217	$ 1,472	$ 705,570	$ (655,640)	$ (27)	$ 51,375
Stock-based compensation expense	—	—	—	—	—	—	2,218	—	—	2,218
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	—	—	—	—	1,038,134	10	4,179	—	—	4,189
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax witholding settlement	—	—	—	—	745,000	3	(3)	—	—	—
Issuance of Series A and Series B Convertible Redeemable Preferred Stock	1,000,006	17,974	250,005	4,494	—	—	—	—	—	—
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	3,026	—	756	—	—	(3,782)	—	—	(3,782)
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(1,000,006)	(21,000)	(250,005)	(5,250)	—	—	—	—	—	—
Reverse stock-split adjustment	—	—	—	—	—	(1,408)	1,408	—	—	—
Net loss	—	—	—	—	—	—	—	(38,570)	—	(38,570)
Other comprehensive loss	—	—	—	—	—	—	—	—	(17)	(17)
Balance at September 30, 2022	—	$ —	—	$ —	7,671,351	$ 77	$ 709,590	$ (694,210)	$ (44)	$ 15,413

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity Continued
(Unaudited)
(In thousands, except share amounts)

Three months ended September 30, 2021

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholde'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2021	4,050,041	$ 1,013	$ 684,987	$ (601,913)	$ (1)	$ 84,086
Stock-based compensation expense	—	—	2,537	—	—	2,537
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	790	—	33	—	—	33
Issuance of common stock in connection with the exercise of stock options	4,878	1	139	—	—	140
Issuance of common stock in connection with restricted share awards, net of cancellations	18,993	5	(5)	—	—	—
Net loss	—	—	—	(7,044)	—	(7,044)
Other comprehensive loss	—	—	—	—	(8)	(8)
Balance at September 30, 2021	4,074,702	$ 1,019	$ 687,691	$ (608,957)	$ (9)	$ 79,744

Nine months ended September 30, 2021

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income/(Loss)	Equity
Balance at December 31, 2020	3,845,267	$ 961	$ 672,304	$ (570,704)	$ (10)	$ 102,551
Stock-based compensation expense	—	—	6,915	—	—	6,915
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	123,332	32	7,667	—	—	7,699
Issuance of common stock in connection with the exercise of stock options	25,227	6	825	—	—	831
Issuance of common stock in connection with restricted share awards, net of cancellations	80,876	20	(20)	—	—	—
Net loss	—	—	—	(38,253)	—	(38,253)
Other comprehensive income	—	—	—	—	1	1
Balance at September 30, 2021	4,074,702	$ 1,019	$ 687,691	$ (608,957)	$ (9)	$ 79,744

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the nine months ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (38,570)	$ (38,253)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,364	2,443
Stock-based compensation expense	2,218	6,915
Non-cash gain on settlement with licensor	—	(6,743)
Non-cash PPP loan payable forgiveness income	—	(1,758)
Non-cash impairment of licensed technology	1,355	—
Non-cash impairment of right-of-use lease asset	1,561	—
Non-cash impairment of construction-in-progress	1,792	—
Accretion and interest on short-term investments	(206)	256
Amortization of right-of-use lease assets	1,204	825
Non-cash interest	558	—
Loss on disposal of property and equipment	121	—
Change in operating assets and liabilities:		
Accounts receivable	3,000	—
Other receivables	(1,047)	—
Prepaid expenses and other current assets	1,432	1,801
Other assets	148	(23)
Accounts payable, accrued expenses and lease liabilities	(5,125)	(4,459)
Deferred revenue	(296)	—
Change in payable to licensor	—	3,588
Net cash used in operating activities	(29,491)	(35,408)
Cash flows from investing activities:		
Capital expenditures	(105)	(903)
Proceeds from disposal of property and equipment	1,590	—
Purchases of short-term investments	(43,866)	(15,164)
Proceeds from maturities of short-term investments	43,707	74,130
Net cash provided by investing activities	1,326	58,063
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	4,189	7,699
Proceeds from exercise of stock options	—	831
Proceeds from issuance of Series A and Series B Convertible Redeemable Preferred Stock, net of issuance costs	22,468	—
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(26,250)	—
Net cash provided by financing activities	407	8,530
Net increase(decrease) in cash, cash equivalents and restricted cash	(27,758)	31,185
Cash, cash equivalents and restricted cash at beginning of period	38,829	13,571
Cash, cash equivalents and restricted cash at end of period	$ 11,071	$ 44,756
Supplemental cash flow information:		
Cash and cash equivalents	$ 5,733	$ 43,781
Restricted cash	5,338	975
Total cash, cash equivalents and restricted cash	$ 11,071	$ 44,756

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

NOTE 1 – NATURE OF OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Background

Abeona Therapeutics Inc. (together with the Company's subsidiaries, "Abeona" or the "Company"), a Delaware corporation, is a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. The Company's lead clinical program is EB-101, an autologous, engineered cell therapy currently in development for recessive dystrophic epidermolysis bullosa ("RDEB"). The Company's development portfolio also features AAV-based gene therapies designed to treat ophthalmic and other diseases, next-generation AAV-based gene therapies using the novel AIM™ capsid platform that the Company has exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

Reverse Stock Split

On June 30, 2022, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Amendment"), to effectuate a reverse stock split of the Company's outstanding common stock, par value $0.01 per share ("Common Stock"), at an exchange ratio of 25-to-1 (the "Reverse Stock Split"). The Reverse Stock Split was effective on July 1, 2022. The number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") remains at 200,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

As a result of the Reverse Stock Split, every 25 shares of Common Stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of New Common Stock without any change in the par value per share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to a fraction of one share of New Common Stock as a result of the Reverse Stock Split instead received an amount in cash equal to such fraction multiplied by the closing sale price of Common Stock on the Nasdaq Capital Market on July 1, 2022, as adjusted for the Reverse Stock Split.

Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at July 1, 2022, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants. In addition, the number of shares reserved for issuance under the Company's 2015 Equity Incentive Plan were reduced proportionately.

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made. These unaudited interim condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The December 31, 2021 condensed consolidated balance sheet was derived from the audited statements, but does not include all disclosures required by U.S. GAAP.

Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 31, 2022.

Uses and Sources of Liquidity

The unaudited interim condensed consolidated financial statements have been prepared on the going concern basis, which assumes the Company will have sufficient cash to pay its operating expenses, as and when they become payable, for a period of at least 12 months from the date the financial report is issued.

As of September 30, 2022, the Company had cash, cash equivalents, restricted cash and short-term investments of $23.5 million. For the nine months ended September 30, 2022, the Company had cash outflows from operations of $29.5 million. The Company has not generated significant revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company's product candidates will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, obtaining the necessary regulatory approval to market the Company's product candidates, raising additional capital to continue to fund the Company's operations, development of competing drugs and therapies and protection of proprietary technology. As a result of these and other risks and the related uncertainties, there can be no assurance of the Company's future success.

The Company believes that its current cash and cash equivalents, restricted cash and short-term investments plus the proceeds from the private placement financing on November 3, 2022 (see Note 12) are sufficient resources to fund operations through at least the next 12 months from the date of this report on Form 10-Q. The Company may need to secure additional funding to carry out all of its planned research and development activities. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on its future prospects.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the unaudited interim condensed consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

Summary of Significant Accounting Policies

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 that are of significance, or potential significance, to the Company, other than the adoption of accounting pronouncements below.

Reclassifications

Certain comparative figures have been reclassified to conform to the current year presentation. The Company reclassified depreciation and amortization costs of $0.8 million and $16,000 to research and development and general and administrative expenses, respectively, on the condensed consolidated statements of operations and comprehensive loss during the three months ended September 30, 2021. The Company reclassified depreciation and amortization costs of $2.4 million and $49,000 to research and development and general and administrative expenses, respectively, on the condensed consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2021. The Company also reclassified certain rent expenses of $0.3 million and $0.9 million from general and administrative to research and development expenses on the condensed consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2021, respectively. Additionally, the Company also reclassified $5.0 million of restricted cash from prepaid expenses, other current assets and restricted cash and $0.9 million of restricted cash from other assets and restricted cash to restricted cash on the condensed consolidated balance sheets as of December 31, 2021.

Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common shareholders by the weighted-average number of shares of common stock. The Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive. Potential dilutive securities result from outstanding restricted stock, stock options, and stock purchase warrants.

The following table sets forth the potential securities that could potentially dilute basic income/(loss) per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the three and nine months ended September 30,	
	2022	2021
Stock options	242,644	310,208
Restricted stock	821,269	114,209
Warrants	1,788,000	—
Total	2,851,913	424,417

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies the accounting for convertible instruments by eliminating the requirement to separately account for embedded conversion features as an equity component in certain circumstances. A convertible debt instrument will be reported as a single liability instrument with no separate accounting for an embedded conversion feature unless separate accounting is required for an embedded conversion feature as a derivative or under the substantial premium model. The ASU simplifies the diluted earnings per share calculation by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. Further, the ASU requires enhanced disclosures about convertible instruments. The Company adopted ASU 2020-06 as of January 1, 2022 and there was no material impact on the condensed consolidated financial statements upon adoption.

NOTE 2 – SHORT-TERM INVESTMENTS

The following table provides a summary of the short-term investments (in thousands):

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments				
U.S. treasury and federal agency securities	$ 12,445	—	(11)	$ 12,434
Total available-for-sale, short-term investments	$ 12,445	—	(11)	$ 12,434

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments				
U.S. treasury securities	$ 12,077	9	—	$ 12,086
Total available-for-sale, short-term investments	$ 12,077	9	—	$ 12,086

As of September 30, 2022, the available-for-sale securities classified as short-term investments mature in one year or less. Unrealized losses on available-for-sale securities as of September 30, 2022 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. None of the short-term investments have been in a continuous unrealized loss position for more than 12 months. Accordingly, no other-than-temporary impairment was recorded for the three or nine months ended September 30, 2022.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three or nine months ended September 30, 2022 or 2021.

NOTE 3 – PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows (in thousands):

	Useful lives (years)	September 30, 2022	December 31, 2021
Laboratory equipment	5	$ 8,144	$ 9,081
Furniture, software and office equipment	3 to 5	1,726	1,896
Leasehold improvements	Shorter of remaining lease term or useful life	8,586	8,603
Construction-in-progress		—	3,219
Subtotal		18,456	22,799
Less: accumulated depreciation		(11,850)	(10,460)
Total property and equipment, net		$ 6,606	$ 12,339

Depreciation expense was $0.8 million for the three months ended September 30, 2022 and 2021, respectively, and $2.3 million and $2.4 million for the nine months ended September 30, 2022 and 2021, respectively. During the three and nine months ended September 30, 2022, the Company incurred a loss on disposal of equipment of $16,000 and $0.1 million, respectively, which is reflected in other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the construction-in-progress that was dedicated to the ABO-101 and ABO-102 programs had no future value, and thus recorded an impairment charge of $1.8 million for the nine months ended September 30, 2022.

NOTE 4 – LICENSED TECHNOLOGY

On May 15, 2015, the Company acquired Abeona Therapeutics LLC, which had an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. The license is amortized over the life of the license of 20 years. On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the remaining value of the licensed technology had no future value and thus recorded an impairment charge of nil and $1.4 million for the three and nine months ended September 30, 2022, respectively.

The following table provides a summary of licensed technology (in thousands):

	September 30, 2022	December 31, 2021
Licensed technology	$ 2,156	$ 2,156
Less accumulated amortization	(801)	(772)
Less impairment charge	(1,355)	—
Total licensed technology, net	$ —	$ 1,384

Amortization expense on licensed technology was nil and $29,000 for the three months ended September 30, 2022 and 2021, respectively and $29,000 and $87,000 for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 5 – SETTLEMENT LIABILITY

On November 12, 2021, the Company entered into a settlement agreement ("Settlement Agreement") with the Company's prior licensor REGENXBIO Inc. ("REGENXBIO") to resolve all existing disputes between the parties. In accordance with the Settlement Agreement, the Company agreed to pay REGENXBIO a total of $30.0 million, payable as follows: (1) $20.0 million paid in November 2021 after execution of the Settlement Agreement, (2) $5.0 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5.0 million upon the earlier of (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement.

As of September 30, 2022, the Company recorded the payables due to REGENXBIO in the condensed consolidated balance sheets based on the present value of the remaining payments due to REGENXBIO under the Settlement Agreement using an interest rate of 9.6%. The current portion of the payable due in November 2022 is $4.9 million and the long-term portion due in November 2024 is $4.1 million as of September 30, 2022. As of September 30, 2022, the Company recorded $5.0 million of restricted cash in the condensed consolidated balance sheet that serves as collateral for the payment owed to REGENXBIO in November 2022.

NOTE 6 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and includes additional information in the notes to the condensed consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, prepaid expenses and other current assets, other assets, accounts payable, accrued expenses, payables to licensor and deferred revenue approximate their carrying amounts due to the relatively short maturity of these instruments.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

The following table provides a summary of financial assets measured at fair value on a recurring and non-recurring basis as of September 30, 2022 and December 31, 2021 (in thousands):

Description	Fair Value at September 30, 2022	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents				
Money market fund	$ 2,312	$ 2,312	$ —	$ —
Short-term investments				
U.S. treasury and federal agency securities	12,434	—	12,434	—
Total assets measured at fair value	$ 14,746	$ 2,312	$ 12,434	$ —

Description	Fair Value at December 31, 2021	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents				
Money market fund	$ 28,590	$ 28,590	$ —	$ —
Short-term investments				
U.S. treasury securities	12,086	—	12,086	—
Total recurring assets	40,676	28,590	12,086	—
Non-recurring Assets				
Licensed technology, net	$ 1,384	$ —	$ —	$ 1,384
Total assets measured at fair value	$ 42,060	$ 28,590	$ 12,086	$ 1,384

NOTE 7 – ACCRUED EXPENSES

The following table provides a summary of the components of accrued expenses (in thousands):

	September 30, 2022	December 31, 2021
Accrued employee compensation	$ 2,092	$ 1,794
Accrued contracted services and other	2,029	3,091
Accrued sublicense fee owed to licensor	—	700
Total accrued expenses	$ 4,121	$ 5,585

NOTE 8 – LEASES

The Company leases space under operating leases for manufacturing and laboratory facilities in Cleveland, Ohio, as well as administrative offices in New York, New York. The Company also leases office space in Madrid, Spain as well as certain office equipment under operating leases, which have a non-cancelable lease term of less than one year and, therefore, the Company has elected the practical expedient to exclude these short-term leases from the Company's right-of-use assets and lease liabilities.

On March 31, 2022, the Company announced that they were pursuing a strategic partner to take over development activities of ABO-102 and that the Company was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the portion of the lease that was dedicated to the future facility for the ABO-101 and ABO-102 programs, had no future value and thus, the Company recorded an impairment charge of nil and $1.6 million for the three and nine months ended September 30, 2022, respectively.

The following table provides a summary of the components of lease costs and rent (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Operating lease cost	$ 467	$ 434	$ 1,400	$ 1,302
Variable lease cost	154	105	366	344
Short-term lease cost	17	13	58	23
Total operating lease costs	$ 638	$ 552	$ 1,824	$ 1,669

Maturities of the Company's operating lease liabilities, which do not include short-term leases, as of September 30, 2022 are as follows:

Maturity of lease liabilities:	*(in thousands)*
Remainder of 2022	$ 446
2023	1,829
2024	1,872
2025	1,631
2026	871
Thereafter	3,662
Total undiscounted operating lease payments	10,311
Less: imputed interest	2,017
Present value of operating lease liabilities	$ 8,294

The weighted-average remaining term of the Company's operating leases was 79 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 7.2% as of September 30, 2022.

NOTE 9 – STOCK-BASED COMPENSATION

The Company has two stock-based compensation plans: (1) Abeona Therapeutics Inc. 2015 Equity Incentive Plan (the "2015 Incentive Plan"), which was approved by stockholders on May 7, 2015 and last amended on May 20, 2020 and (2) Abeona Therapeutics Inc. 2005 Equity Incentive Plan (the "2005 Incentive Plan"), under which no further grants can be made.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the three months ended September 30,		**For the nine months ended September 30**	
	2022	**2021**	**2022**	**2021**
Research and development	$ 173	$ 688	$ 729	$ 2,935
General and administrative	459	1,849	1,489	3,980
Total stock-based compensation expense	$ 632	$ 2,537	$ 2,218	$ 6,915

Stock Options*:* The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option valuation model. The Company then recognize the grant date fair value of each option as compensation expense ratably using the straight-line attribution method over the service period (generally the vesting period). The Black-Scholes model incorporates the following assumptions:

- Expected volatility – the Company estimates the volatility of the share price at the date of grant using a "look-back" period which coincides with the expected term, defined below. The Company believes using a "look-back" period which coincides with the expected term is the most appropriate measure for determining expected volatility.
- Expected term – the Company estimates the expected term using the "simplified" method, as outlined in SEC Staff Accounting Bulletin No. 107, "Share-Based Payment."
- Risk-free interest rate – the Company estimates the risk-free interest rate using the U.S. Treasury yield curve for periods equal to the expected term of the options in effect at the time of grant.
- Dividends – the Company uses an expected dividend yield of zero because the Company has not declared nor paid a cash dividend, nor are there any plans to declare a dividend.

The Company estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-valuation model utilizing the following assumptions:

	For the nine months ended September 30,	
	2022	2021
Expected volatility	95.1% - 96.0%	91.8% - 99.8%
Expected term	6.07 - 6.08 years	5.25 - 6.08 years
Risk-free interest rate	1.7% - 3.3%	0.8% - 1.2%
Expected dividend yield	—	—

The following table summarizes stock option activity for the 2015 Incentive Plan during the nine months ended September 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	314,194	$ 38.48	7.63	$ —
Granted	7,760	$ 5.30	—	$ —
Cancelled/forfeited	(82,510)	$ 39.31	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at September 30, 2022	239,444	$ 37.10	6.71	$ —
Exercisable	140,414	$ 36.67	5.39	$ —
Unvested	99,030	$ 37.72	8.58	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2022, the total compensation cost related to non-vested option awards not yet recognized was approximately $3.3 million with a weighted average remaining vesting period of 2.3 years.

The following table summarizes stock option activity for the 2005 Incentive Plan during the nine months ended September 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	3,200	$ 32.00	1.80	$ —
Cancelled/forfeited	—	$ —	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at September 30, 2022	3,200	$ 32.00	1.04	$ —
Exercisable	3,200	$ 32.00	1.04	$ —
Unvested	—	$ —	—	$ —

Restricted Stock:

The following table summarizes restricted stock award activity during the nine months ended September 30, 2022:

	Number of Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	97,260	$ 46.59
Granted	779,722	$ 3.12
Cancelled/forfeited	(30,742)	$ 40.65
Vested	(24,971)	$ 50.66
Outstanding at September 30, 2022	821,269	$ 5.42

As of September 30, 2022, there was approximately $4.1 million of total unrecognized compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted average vesting period of 3.1 years. The total fair value of restricted stock awards that vested during the nine months ended September 30, 2022 was $1.3 million.

NOTE 10 – EQUITY

Series A and B Convertible Redeemable Preferred Stock

On May 2, 2022, the Company consummated an offering with certain institutional investors for the private placement of 1,000,006 shares of the Company's Series A Convertible Redeemable Preferred Stock (the "Series A Preferred Stock") and 250,005 shares of the Company's Series B Convertible Redeemable Preferred Stock (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Preferred Stock"). The shares, which have since been redeemed in accordance with their terms described below, and are thus no longer outstanding as of September 30, 2022, had an aggregated stated value of $25.0 million. Each share of the Preferred Stock had a purchase price of $19.00, representing an original issue discount of 5% of the stated value. In connection with this offering, the Company had net proceeds of $22.5 million and recognized a deemed dividend of $3.8 million. In connection with this transaction, the Company placed $26.3 million into an escrow account for any future redemption which consisted of the gross proceeds of $25.0 million and the redemption value of $1.3 million.

The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $11.25 per share. The holders of the Series A Preferred Stock and Series B Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the receipt of stockholder approval of an amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split and 60 days after the closing of the issuances of the Series A Preferred Stock and Series B Preferred Stock and until 90 days after such closing. The Company had the option to redeem the Series A Preferred Stock for cash at 105% of the stated value commencing after the 90th day following the closing of the issuance of the Series A Preferred Stock, subject to the holders' rights to convert the shares prior to such redemption. As a result, the Preferred Stock was recorded separately from stockholders' equity because it was redeemable upon the occurrence of redemption events that were considered not solely withing the Company's control. As such, during the nine months ended September 30, 2022, the Company recognized approximately $3.8 million in deemed dividends related to the Preferred Stock in the condensed consolidated statements of operations and comprehensive loss and the condensed consolidated statements of changes in stockholders' equity.

On June 17, 2022, the holders of all 1,000,006 shares of Series A Preferred Stock and 250,005 shares of Series B Preferred Stock exercised their right to cause the Company to redeem all such shares for $26.3 million, which represented a price equal to 105% of the stated value. The redemption of these shares was paid out of the escrow account noted above.

Common Stock and Warrants

Reverse Stock Split

Effective July 1, 2022, the Company's stock underwent a 25:1 Reverse Stock Split. The number of authorized shares of Common Stock immediately after the Reverse Stock Split remained at 200,000,000 shares.

Public Offerings

On December 21, 2021, the Company closed an underwritten public offering of 1,788,000 post-split shares of common stock at a public offering price of $9.75 post-split per share and stock purchase warrants to purchase 1,788,000 post-split shares of common stock at an exercise price of $9.75 post-split. The net proceeds to the Company were approximately $16.0 million, after deducting $1.5 million of underwriting discounts and commissions and offering expenses payable by the Company.

As of September 30, 2022, there were 1,788,000 post-split stock purchase warrants outstanding. These stock purchase warrants expire on December 21, 2026. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. There was no warrant activity during the three or nine months ended September 30, 2022.

Open Market Sale Agreement

On August 17, 2018 the Company entered into an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, the Company may sell from time to time, through Jefferies LLC, shares of its common stock for an aggregate sales price of up to $150.0 million. Any sales of shares pursuant to this agreement are made under the Company's effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC. The Company is currently subject to General Instruction I.B.6 of Form S-3, as a result of which the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. The Company remains subject to this one-third limitation until such time as its public float exceeds $75 million. The Company sold 1,038,134 shares of its common stock under the ATM Agreement and received $4.2 million of net proceeds during the nine months ended September 30, 2022. Subsequent to September 30, 2022, the Company sold an additional 2,440,882 shares of its common stock under the ATM Agreement and received $8.6 million of net proceeds.

NOTE 11 – LICENSE AGREEMENT

On May 16, 2022, the Company and Ultragenyx Pharmaceutical Inc. ("Ultragenyx") entered into an exclusive license agreement (the "License Agreement") for AAV gene therapy ABO-102 for the treatment of Sanfilippo syndrome type A (MPS IIIA). Under the License Agreement, Ultragenyx will assume responsibility for the ABO-102 program from the Company, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, the Company is eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments. Both forms of consideration comprise the transaction price to which the Company expects to be entitled in exchange for transferring the related intellectual property and certain, contractually-specified transition services to Ultragenyx. The sales-based royalty and milestone payments are subject to the royalty recognition constraint. As such, these fees are not recognized as revenue until the later of: (a) the occurrence of the subsequent sale, and (b) the performance obligation to which they relate has been satisfied.

Additionally, pursuant to the License Agreement, Ultragenyx will reimburse the Company for certain development and transition costs actually incurred by the Company. These costs are passed through to Ultragenyx without mark-up. The Company has determined that these costs are not incurred for the purpose of satisfying any performance obligation under the License Agreement. Accordingly, the reimbursement of these costs is recognized as a reduction of research and development costs. Such amounts due to the Company from Ultragenyx under the License Agreement of $0.8 million are recorded as a component of other receivables in the condensed consolidated balance sheet as of September 30, 2022.

NOTE 12 – SUBSEQUENT EVENTS

On November 3, 2022 the Company announced that it has entered into a securities purchase agreement to sell 7,065,946 shares of its common stock, and, in lieu of shares of common stock, pre-funded warrants exercisable for 543,933 shares of common stock, and accompanying warrants to purchase 7,609,879 shares of its common stock to a group of new and existing institutional investors in a private placement. The offering price for each share of common stock and accompanying warrant was $4.60, and the offering price for each pre-funded warrant and accompanying warrant was $4.59, which equals the offering price per share of the common stock and accompanying warrant, less the $0.01 per share exercise price of each pre-funded warrant. Each accompanying warrant will represent the right to purchase one share of the Company's common stock at an exercise price of $4.75 per share of common stock. The pre-funded warrants and the accompanying warrants will be exercisable immediately, and will expire five years from the date of issuance. Gross proceeds of the private placement are expected to be approximately $35.0 million, before deducting placement agent fees and other expenses.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"). This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Forward-Looking Statements," "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

OVERVIEW

Abeona Therapeutics Inc. ("we," "our," "Abeona" or the "Company") is a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. Our lead clinical program is EB-101, an autologous, engineered cell therapy currently in development for recessive dystrophic epidermolysis bullosa ("RDEB").

Our development portfolio also features AAV-based gene therapies designed to treat ophthalmic and other diseases, next-generation AAV-based gene therapies using the novel AIM™ capsid platform that we have exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

RECENT DEVELOPMENTS

EB-101 (Autologous, Engineered Cell Therapy) for RDEB

On November 3, 2022, we announced positive topline data from VIITAL™ study. The pivotal Phase 3 VIITAL™ study evaluated the efficacy, safety and tolerability of EB-101 in 43 large chronic wound pairs in 11 subjects with RDEB. The large chronic wounds randomized and treated in VIITAL™ measured greater than 20 cm^2 of surface area and had remained open for a minimum of six months and a maximum of 21 years (mean 6.2 years). The co-primary endpoints of the study were: (1) the proportion of RDEB wound sites with greater than or equal to 50% healing from baseline, comparing randomized treated with matched untreated (control) wound sites at the six-month timepoint, as determined by direct investigator assessment; and (2) pain reduction associated with wound dressing change assessed by the mean differences in scores of the Wong-Baker FACES scale between randomized treated and matched untreated (control) wounds at the six-month timepoint.

The VIITAL™ study met its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction in large chronic RDEB wounds. EB-101 was shown to be well-tolerated with no serious treatment-related adverse events observed, consistent with past clinical experience. There were no deaths or instances of positive replication-competent retrovirus results, and no systemic immunologic responses were reported during the study, as well as no squamous cell carcinoma at treatment sites after application of EB-101. Two subjects reported at least one serious adverse event unrelated to EB-101. Four subjects reported related treatment emergent adverse events, including procedural pain, muscle spasms and pruritis. Infections unrelated to EB-101 were observed in eight patients.

Based on the positive topline results, we intend to submit a Biologics License Application ("BLA") for EB-101 to the U.S. Food and Drug Administration ("FDA") in the second quarter of 2023. EB-101 has been granted Orphan Drug and Rare Pediatric Disease ("RPD") designations by the FDA. Among the potential benefits of Orphan Drug designation are a potential seven years of market exclusivity following FDA approval, potentially preventing FDA approval of another product deemed to be the same as the approved product for the same indication, waiver of application fees, and tax credits for qualified clinical testing expenses conducted after orphan designation is received. A sponsor who receives an approval for a BLA with RPD designation may qualify for a Priority Review Voucher ("PRV"), subject to final determination by the FDA. A PRV may be used to receive expedited review of a subsequent marketing application for a different product or sold to another company.

We have continued to prepare our current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing EB-101 drug product to support our planned BLA filing to the FDA. EB-101 study drug product for all our VIITAL™ study participants has been manufactured at our Cleveland facility and we completed submission of Module 3 for Chemistry, Manufacturing and Controls ("CMC") describing the in-house production of both retroviral vector and the final drug product to the Investigational New Drug Application ("IND") in December 2021. Based on feedback from the FDA in a Type-B meeting in March 2022, we believe that we have alignment with the FDA on significant components of the CMC plan for the BLA submission for EB-101, including characterization and validation plans.

Ultragenyx License Agreement

On May 16, 2022, we entered into an exclusive license agreement (the "License Agreement") with Ultragenyx Pharmaceutical Inc. ("Ultragenyx") for our investigational AAV gene therapy ABO-102 for the treatment of Sanfilippo syndrome type A ("ABO-102"). Under the License Agreement, Ultragenyx will assume responsibility for the ABO-102 program from us, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, we are eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments.

Preclinical Pipeline

While our lead clinical program is currently focused on an ultra-rare indication, we intend to address larger areas of unmet medical need in the future, and our preclinical programs are investigating the use of novel AAV capsids in AAV-based therapies for five undisclosed ophthalmic conditions each with estimated U.S. prevalence ranging from 5,000 to 15,000 patients. In 2021, we shared data from studies in non-human primates that will help to determine optimal routes of administration and we believe we have made significant progress toward measuring efficacy in the preclinical setting. We have also generated appropriate mouse models, produced research grade vectors, and started dosing mice in proof-of-concept studies that we hope will support pre-IND meetings with the FDA in early 2023.

Private Placement Financing

On November 3, 2022, we entered into a securities purchase agreement to sell 7,065,946 shares of our common stock, and, in lieu of shares of common stock, pre-funded warrants exercisable for 543,933 shares of common stock, and accompanying warrants to purchase 7,609,879 shares of our common stock to a group of new and existing institutional investors in a private placement. The offering price for each share of common stock and accompanying warrant was $4.60, and the offering price for each pre-funded warrant and accompanying warrant was $4.59, which equals the offering price per share of the common stock and accompanying warrant, less the $0.01 per share exercise price of each pre-funded warrant. Each accompanying warrant will represent the right to purchase one share of the our common stock at an exercise price of $4.75 per share of common stock. The pre-funded warrants and the accompanying warrants will be exercisable immediately, and will expire five years from the date of issuance. Gross proceeds of the private placement are expected to be approximately $35.0 million, before deducting placement agent fees and other expenses. We intend to use the net proceeds from the proposed private placement for development, working capital and general corporate purposes.

Preferred Stock Offering

On May 2, 2022, we consummated an offering with certain institutional investors for the private placement of 1,000,006 shares of our Series A Convertible Redeemable Preferred Stock (the "Series A Preferred Stock") and 250,005 shares of our Series B Convertible Redeemable Preferred Stock (the "Series B Preferred Stock, and together with the Series A Preferred Stock, the "Preferred Stock"). The shares, which have since been redeemed in accordance with their terms described below, and are thus no longer outstanding as of September 30, 2022, had an aggregated stated value of $25.0 million. Each share of Preferred Stock had a purchase price of $19.00, representing an original issue discount of 5% of the stated value. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by us, into shares of Common Stock at a conversion price of $11.25 per share. The holders of the Preferred Stock had the right to require us to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the receipt of stockholder approval of an amendment to our Restated Certificate of Incorporation to effect a reverse stock split and 60 days after the closing of the issuances of the Series A Preferred Stock and Series B Preferred Stock and until 90 days after such closing. We had the option to redeem the Series A Preferred Stock for cash at 105% of the stated value commencing after the 90th day following the closing of the issuance of the Series A Preferred Stock, subject to the holders' rights to convert the shares prior to such redemption. On June 17, 2022, the holders of all 1,000,006 shares of Series A Preferred Stock and all 250,005 shares of Series B Preferred Stock exercised their right to cause us to redeem all of such shares at a price equal to 105% of the stated value.

Reverse Stock Split

On June 30, 2022, we filed a Certificate of Amendment to our Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effectuate a reverse stock split of our outstanding common stock, par value $0.01 per share at an exchange ratio of 25-to-1 (the "Reverse Stock Split"). The Reverse Stock Split was effective on July 1, 2022. The number of authorized shares of our common stock immediately after the Reverse Stock Split remained at 200,000,000 shares.

Open Market Sale Agreement

We sold 1,038,134 shares of our common stock under the ATM Agreement (as defined below) and received $4.2 million of net proceeds during the nine months ended September 30, 2022. Subsequent to September 30, 2022, we sold an additional 2,440,882 shares of our common stock under the ATM Agreement and received $8.6 million of net proceeds.

Nasdaq Compliance

On November 16, 2021, we had received a deficiency letter from the Nasdaq Stock Market ("Nasdaq") informing that our common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement") based on the closing bid price of the common stock for the 30 consecutive business days prior to the date of the notice. Following the effectuation of our Reverse Stock Split on July 19, 2022, we received formal notification from Nasdaq confirming that we had regained compliance with the Bid Price Requirement.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2022 and September 30, 2021

	For the three months ended		Change	
($ in thousands)	September 30, 2022	September 30, 2021	$	%
Expenses:				
Research and development	$ 5,490	$ 9,056	$ (3,566)	(39)%
General and administrative	3,890	5,816	(1,926)	(33)%
Total expenses	9,380	14,872	(5,492)	(37)%
Loss from operations	(9,380)	(14,872)	5,492	(37)%
Gain on settlement with licensor	—	6,743	(6,743)	N/A
PPP loan payable forgiveness income	—	1,758	(1,758)	N/A
Interest income	72	7	65	929%
Interest expense	(157)	(683)	526	(77)%
Other income (expense)	(19)	3	(22)	(733)%
Net loss	$ (9,484)	$ (7,044)	$ (2,440)	35%

N/A - not applicable or not meaningful

Research and development

Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical and development costs, clinical trial costs, manufacturing and manufacturing facility costs, costs associated with regulatory approvals, depreciation on lab supplies and manufacturing facilities, and consultant-related expenses.

Total research and development spending for the three months ended September 30, 2022 was $5.5 million, as compared to $9.1 million for the same period of 2021, a decrease of $3.6 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our cell and gene therapy product candidates and other related costs of $1.4 million which is net of the $1.2 million pass through costs to Ultragenyx;
- decreased salary and related costs of $0.4 million; and
- decreased non-cash stock compensation expenses of $0.5 million.

We expect our research and development activities to continue as we attempt to advance our product candidates towards potential regulatory approval, reflecting costs associated with:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

General and administrative

General and administrative expenses primarily consist of payroll and personnel costs, office facility costs, public reporting company related costs, professional expenses (e.g., legal expenses) and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were $3.9 million for the three months ended September 30, 2022, as compared to $5.8 million for the same period of 2021, a decrease of $1.9 million. The decrease in expenses was primarily due to:

- decreased professional fees of $0.8 million;
- decreased non-cash stock-based compensation of $1.4 million; and
- decreased other costs of $0.2 million; partially offset by
- increased salary and related costs of $0.5 million.

Gain on settlement with licensor

Gain on settlement with licensor was nil for the three months ended September 30, 2022, as compared to $6.7 million in the same period of 2021. On November 12, 2021, we entered into a Settlement Agreement with REGENXBIO Inc. (“REGENXBIO”) to resolve all current disputes between us and REGENXBIO (the “Settlement Agreement”). The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with REGENXBIO in the first three months of 2021.

PPP loan payable forgiveness income

Paycheck Protection Program (“PPP”) loan payable forgiveness income was nil for the three months ended September 30, 2022 as compared to $1.8 million in the same period of 2021. In July 2021, we received notice from the Small Business Administration (“SBA”) that our PPP loan had been forgiven so the PPP loan payable was reversed in the first three months of 2021.

Interest income

Interest income was $72,000 for the three months ended September 30, 2022, as compared to $7,000 in the same period of 2021. The increase resulted from higher earnings on short-term investments driven by higher interest rates partially offset by a lower average balance of short-term investments.

Interest expense

Interest expense was $0.2 million for the three months ended September 30, 2022, as compared to $0.7 million in the same period of 2021. The decrease results primarily from the resolution of a disputed liability owed to our prior licensor, REGENXBIO.

Other income (expense)

Other income (expense) was ($19,000) for the three months ended September 30, 2022, as compared to $3,000 in the same period of 2021. The decrease results primarily from the loss on disposal of fixed assets.

Comparison of Nine Months Ended September 30, 2022 and September 30, 2021

	For the nine months ended		Change	
($ in thousands)	September 30, 2022	September 30, 2021	$	%
Revenues:				
License and other revenues	$ 1,346	$ —	$ 1,346	N/A
Expenses:				
Royalties	350	—	350	N/A
Research and development	22,693	25,923	(3,230)	(12)%
General and administrative	11,574	17,261	(5,687)	(33)%
Impairment of licensed technology	1,355	—	1,355	N/A
Impairment of right-of-use lease asset	1,561	—	1,561	N/A
Impairment of construction-in-progress	1,792	—	1,792	N/A
Total expenses	39,325	43,184	(3,859)	(9)%
Loss from operations	(37,979)	(43,184)	5,205	(12)%
Gain on settlement with licensor	—	6,743	(6,743)	N/A
PPP loan payable forgiveness income	—	1,758	(1,758)	N/A
Interest income	103	35	68	194%
Interest expense	(558)	(3,603)	3,045	(85)%
Other expense	(136)	(2)	(134)	6,700%
Net loss	$ (38,570)	$ (38,253)	$ (317)	1%

N/A - not applicable or not meaningful

License and other revenues

License and other revenues for the nine months ended September 30, 2022 was $1.3 million, as compared to nil for the same period of 2021. The revenue in 2022 resulted from a clinical milestone achieved in the second quarter of 2022 under a sublicense agreement we entered into with Taysha Gene Therapies ("Taysha") in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome, including certain intellectual property relating to MECP2 gene constructs and regulation of their expression. There was also revenue consisting of the recognition of deferred revenue related to grants for the ABO-102 and ABO-101 development programs.

Royalties

Total royalties expenses were $0.4 million for the nine months ended September 30, 2022, as compared to nil for the same period of 2021, an increase of $0.4 million. The increase in expense was due to royalties owed to our licensors resulting from the $1.0 million milestone due from Taysha.

Research and development

Total research and development spending for the nine months ended September 30, 2022 was $22.7 million, as compared to $25.9 million for the same period of 2021, a decrease of $3.2 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our cell and gene therapy product candidates and other related costs of $0.8 million which primarily relates to the license out/discontinuation of our MPSIII programs;
- decreased non-cash stock compensation expenses of $2.2 million; and
- decreased salary and related costs of $0.4 million; partially offset by
- increased other costs of $0.2 million.

General and administrative

Total general and administrative expenses were $11.6 million for the nine months ended September 30, 2022, as compared to $17.3 million for the same period of 2021, a decrease of $5.7 million. The decrease in expenses was primarily due to:

- decreased professional fees of $4.0 million; and
- decreased non-cash stock-based compensation of $2.5 million; partially offset by
- increased salary and related costs of $0.7 million.

Impairment of licensed technology

Impairment of licensed technology was $1.4 million for the nine months ended September 30, 2022, as compared to nil in the same period of 2021. The licensed technology was for the ABO-102 and ABO-101 development programs, which, as a result of our shift in priorities, we determined the remaining value of the licensed technology had no future value and thus recorded impairment of $1.4 million for the nine months ended September 30, 2022.

Impairment of right-of-use lease asset

Impairment of right-of-use lease asset was $1.6 million for the nine months ended September 30, 2022, as compared to nil in the same period of 2021. The impairment was related to a lease for a future manufacturing facility for the ABO-102 and ABO-101 development programs, which, as a result of our shift in priorities, we determined the remaining value of the portion of this lease had no future value and thus recorded impairment of $1.6 million for the nine months ended September 30, 2022.

Impairment of construction-in-progress

Impairment of construction-in-progress was $1.8 million for the nine months ended September 30, 2022, as compared to nil in the same period of 2021. The construction-in-progress was for a facility for the ABO-102 and ABO-101 development programs. As a result of our shift in priorities, we determined the remaining value of the construction-in-progress facility had no future value and thus recorded impairment of $1.8 million for the nine months ended September 30, 2022.

Gain on settlement with licensor

Gain on settlement with licensor was nil for the nine months ended September 30, 2022, as compared to $6.7 million in the same period of 2021. On November 12, 2021, we entered into a Settlement Agreement with REGENXBIO to resolve all current disputes between us and REGENXBIO. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with REGENXBIO in the first nine months of 2021.

PPP loan payable forgiveness income

PPP loan payable forgiveness income was nil for the nine months ended September 30, 2022 as compared to $1.8 million in the same period of 2021. In July 2021, we received notice from the SBA that our PPP loan had been forgiven so the PPP loan payable was reversed in the first nine months of 2021.

Interest income

Interest income was $103,000 for the nine months ended September 30, 2022, as compared to $35,000 in the same period of 2021. The increase resulted from higher earnings on short-term investments driven by higher interest rates partially offset by a lower average balance of short-term investments.

Interest expense

Interest expense was $0.6 million for the nine months ended September 30, 2022, as compared to $3.6 million in the same period of 2021. The decrease results primarily from the resolution of a disputed liability owed to our prior licensor, REGENXBIO.

Other expense

Other expense was ($136,000) for the nine months ended September 30, 2022, as compared to ($2,000) in the same period of 2021. The decrease results primarily from the loss on disposal of fixed assets.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Nine months Ended September 30, 2022 and 2021

($ in thousands)	For the nine months ended September 30, 2022	2021
Total cash and cash equivalents (used in)/provided by:		
Operating activities	$ (29,491)	$ (35,408)
Investing activities	1,326	58,063
Financing activities	407	8,530
Net (decrease) increase in cash and cash equivalents	$ (27,758)	$ 31,185

Operating activities

Net cash used in operating activities was $29.5 million for the nine months ended September 30, 2022, primarily comprised of our net loss of $38.6 million and a decrease in operating assets and liabilities of $1.9 million, partially offset by net non-cash charges of $11.0 million.

Net cash used in operating activities was $35.4 million for the nine months ended September 30, 2021, primarily comprised of our net loss of $38.3 million, partially offset by an increase in operating assets and liabilities of $0.9 million and net non-cash charges of $1.9 million.

Investing activities

Net cash provided by investing activities was $1.3 million for the nine months ended September 30, 2022, primarily comprised of proceeds from maturities of short-term investments of $43.7 million and proceeds from disposal of property and equipment of $1.6 million, partially offset by purchases of short-term investments of $43.9 million and capital expenditures of $0.1 million.

Net cash provided by investing activities was $58.1 million for the nine months ended September 30, 2021, primarily comprised of proceeds from maturities of short-term investments of $74.1 million, partially offset by purchases of short-term investments of $15.2 million and capital expenditures of $0.9 million.

Financing activities

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2022, primarily comprised of proceeds of $4.2 million from open market sales of common stock pursuant to the ATM Agreement (as defined below), partially offset by the proceeds and redemption of our convertible redeemable preferred stock.

Net cash provided by financing activities was $8.5 million for the nine months ended September 30, 2021, primarily comprised of proceeds of $7.7 million from open market sales of common stock pursuant to the ATM Agreement and proceeds of $0.8 million from the exercise of stock options.

We have historically funded our operations primarily through sales of common stock.

Our principal source of liquidity is cash, cash equivalents, restricted cash and short-term investments, collectively referred to as our cash resources. As of September 30, 2022, our cash resources were $23.5 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments plus the net proceeds from the private placement financing on November 3, 2022 are sufficient resources to fund operations through at least the next 12 months from the date of this report on Form 10-Q. We may need to secure additional funding to carry out all of our planned research and development activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

We have an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, we may sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $150.0 million. Any sales of shares pursuant to this agreement are made under our effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We are currently subject to General Instruction I.B.6 of Form S-3, as a result of which the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We remain subject to this one-third limitation until such time our public float exceeds $75 million. We sold 1,038,134 shares of our common stock under the ATM Agreement and received $4.2 million of net proceeds during the nine months ended September 30, 2022. Subsequent to September 30, 2022, we sold an additional 2,440,882 shares of our common stock under the ATM Agreement and received $8.6 million of net proceeds

Since our inception, we have incurred negative cash flows from operations and have expended, and expect to continue to expend, substantial funds to complete our planned product development efforts. We have not been profitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials, and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted, and the new investors could obtain terms more favorable than previous investors. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

We are carefully and continually reassessing key business activities and all associated spending decisions. Nonetheless, we are spending necessary funds on manufacturing activities and preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds depend on many factors, including:

- the successful development, regulatory approval and commercialization of our cell and gene therapy and other product candidates;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development, and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting, and enforcing patent claims;
- the costs involved in conducting clinical trials;
- any continuing impact to our business, operations, and clinical programs from the COVID-19 pandemic and government actions related thereto;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- the successful outcome of our regulatory filings.

Due to uncertainties and certain of the risks described above, our ability to successfully commercialize our product candidates, our ability to obtain applicable regulatory approval to market our product candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, the potential necessity of licensing technology from third parties and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risks above.

We plan to continue our policy of investing any available funds in suitable certificates of deposit, money market funds, government securities and investment-grade, interest-bearing securities. We do not invest in derivative financial instruments.

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have a material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. For a discussion of the critical accounting estimates that affect the unaudited condensed consolidated financial statements, see "Critical Accounting Estimates" included in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

See Note 1 to our unaudited condensed consolidated financial statements for a discussion of our significant accounting policies.

Recently Issued Accounting Standards Not Yet Effective or Adopted

See Note 1 to our unaudited condensed consolidated financial statements for a discussion of recently issued accounting standards not yet effective or adopted.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of September 30, 2022, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Conclusion of Evaluation — Based on this Disclosure Controls and Procedures evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our Disclosure Controls and Procedures as of September 30, 2022 were effective.

Changes in Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 should be carefully considered. There have been no material changes in the assessment of other risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2021.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) The following table provides information about purchases of equity securities that are registered pursuant to Section 12 of the Exchange Act for the quarter ended September 30, 2022:

	Total number of shares (or units) purchased [(a)]	Average price paid per share (or unit)
Shares delivered or withheld pursuant to restricted stock awards		
July 1, 2022 - July 31, 2022	—	$ —
August 1, 2022 - August 31, 2022	—	$ —
September 1, 2022 - September 30, 2022	479	$ 3.72
	479	$ 3.72

(a) Reflects shares of common stock surrendered to the Company for payment of tax withholding obligations in connection with the vesting of restricted stock.

ITEM 6. EXHIBITS

See Exhibit Index below, which is incorporated by reference herein.

Exhibit Index

Exhibits:

31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2022 and December 31, 2021, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2022 and 2021, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2022 and 2021, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021, and (v) Notes to Condensed Consolidated Financial Statements.

* Pursuant to Item 601(b)(32)(ii) of Regulation S-K, this exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ABEONA THERAPEUTICS INC.

Date: November 14, 2022

By: */s/ Vishwas Seshadri*

Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2022

By: */s/ Joseph Vazzano*

Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2022, of Abeona Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2022, of Abeona Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Joseph Vazzano, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2022

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)